

Applicants: William R. Jacobs, Jr., Tsungda Hsu, Stoyan Bardanov,  
Vasan Sambandamurthy and Sheldon Morris  
Appl. No.: 10/542,958  
Filed: January 30, 2007  
page 4 of 5

#### Remarks

Claims 1, 5, 8, 10, 19, 41 and 87 are pending in the subject application. By this amendment, Claim 1 has been amended to further define applicants' invention and new Claims 88 and 89 have been added. The amendments to Claim 1 and new Claims 88 and 89 are supported by the application as filed and do not introduce new matter. More specifically, the amendments to Claim 1 and new Claims 88 and 89 are supported, for example, in the application at page 13, line 25 and page 63, lines 9-26. Accordingly, entry of the foregoing claim amendments is respectfully requested.

#### Rejection Under 35 U.S.C. §112, First Paragraph

Claims 1, 5, 8, 10, 19, 41 and 87 were rejected under 35 U.S.C. §112, first paragraph. This rejection is respectfully traversed.

In the Office Action, the Examiner stated that the claimed invention lacks enablement for inoculating any mammal other than a mouse against *M. tuberculosis* using an attenuated *M. tuberculosis* or *M. bovis* which has a deletion of RD1 and is auxotrophic for pantothenate. In this regard, the Examiner focused on statements in Waters, et al. that "vaccination trials with m<sup>2</sup>6030 failed to protect cynomolgus monkeys from virulent *M. tuberculosis*." It is noted, however, that Water, et al. stated that "[s]imilar findings with cynomolgus monkey and neonatal calf trials, however, may be indicative of other, non-determined causes of vaccine failure such as inappropriate dose." (see, Waters, et al., page 7839, first paragraph). Claim 1 recites that the attenuated *M. tuberculosis* or *M. bovis* mycobacterium is administered in an "amount" "effective to confer protection against *Mycobacterium tuberculosis* in the mammal". In addition, it is noted that the claimed method provides that the mammal is immunocompromised. Waters does not state that its animals were immunocompromised.

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page 5 of 5

In view of the teachings in the specification that an attenuated mycobacterium having a deletion of RD1 that is auxotrophic for pantothenate, or an attenuated mycobacterium that is auxotrophic for both lysine and pantothenate, can be administered in an amount effective to confer protection against *M. tuberculosis* in an immunocompromised mammal, the claimed invention is believed to be enabled. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

### CONCLUSIONS

In view of the amendments and remarks made hereinabove, reconsideration and withdrawal of the rejections set forth in the July 1, 2010 Office Action and passage of the pending claims to allowance are respectfully requested. If there is any minor matter preventing the allowance of the subject application, the Examiner is requested to telephone the undersigned attorney.

No fee, other than the \$1175 five month extension of time fee and the \$405 RCE fee, is deemed necessary in connection with the filing of this Amendment. However, if any fee is required to preserve the pendency of the subject application, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 01-1785. Overpayments may also be credited to Deposit Account No. 01-1785.

Respectfully submitted

AMSTER, ROTHSTEIN & EBENSTEIN LLP  
Attorneys for Applicants  
90 Park Avenue  
New York, NY 10016  
(212) 336-8000

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By: /Craig J. Arnold/  
Craig J. Arnold  
Registration No. 34,287